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May 31, 2006

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Kevin J. Tracey

Application No.: 10/535,267 Group Art Unit: 1642

Filed: November 22, 2005 Examiner: Not Assigned

Confirmation No.: 6690

Title: USE OF HMGB POLYPEPTIDES FOR INCREASING IMMUNE RESPONSES

CERTIFICATE OF MAILING OR TRANSMISSION

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May 31, 2006 Carried.

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CHRISTINE A. RUDO

Typed or printed name of person signing certificate

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- [] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

- [X] Copies of the cited references, B1-B8 and C1-C80, are enclosed.
 - [X] Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - [] Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- [X] The listed references (A1, C1-C4) were cited in the enclosed International Search Report in a counterpart foreign application.
- [X] The "concise explanation" requirement (non-English references) for references B5 and B8 under 37 CFR 1.98(a)(3) is satisfied by:
 - [] the explanation provided on the attached sheet.
 - [] the explanation provided in the Specification.
 - [] submission of the enclosed International Search Report.
 - [] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- [X] the enclosed English language abstract.

[] Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: May 31, 2006

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

May 31, 2006

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
3268.1003-004APPLICATION NO.
10/535,267FIRST NAMED INVENTOR
Kevin J. TraceyFILING DATE
November 22, 2005EXAMINER
Not AssignedCONFIRMATION NO.
6690GROUP
1642

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
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	A2	6,303,321 B1	10/16/2001	Tracey, K. J. and Wang, H.
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EXAMINER

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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 31, 2006 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 3268.1003-004	APPLICATION NO. 10/535,267
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		EXAMINER Not Assigned	CONFIRMATION NO. 6690
			GROUP 1642

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	B1	WO 00/47104	08/17/2000	The Picower Institute for Medical Research	
	B2	WO 99/59609	11/25/1999	Bartorelli, A.	
	B3	WO 02/074337 A1	09/26/2002	Bianchi, M. E., <i>et al.</i>	
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	B6	EP 1 079 849 B1	01/02/2002	Bartorelli, A.	
	B7	WO 96/25493	08/22/1996	Bullerdiek, J.	
	B8	WO 97/23611	07/03/1997	Bullerdiek, J.	X
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OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)			
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C6	Abraham, E., <i>et al.</i> , "Cutting Edge: HMG-1 as a Mediator of Acute Lung Inflammation," <i>J. Immunol.</i> , 165:2950-2954 (2000).		
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OTHER DOCUMENTS (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)			
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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

C44	Sobajima, J., <i>et al.</i> , "Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in Ulcerative Colitis: Anti-Cathepsin G and a Novel Antibody Correlate With a Refractory Type," <i>Clin. Exp. Immunol.</i> , 105:120-124 (1996).
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C50	Uesugi, H., <i>et al.</i> , "Prevalence and Characterization of Novel pANCA, Antibodies to the High Mobility Group Non-Histone Chromosomal Proteins HMG1 and HMG2, in Systemic Rheumatic Diseases," <i>J. Rheumatol.</i> , 25(4):703-709 (1998).
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C52	Wang, H., <i>et al.</i> , "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice," <i>Science</i> , 285:248-251 (1999).
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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

C54	Yamawaki, M., <i>et al.</i> , "Generation and Characterization of Anti-Sulfoglucuronosyl Paragloboside Monoclonal Antibody NGR50 and its Immunoreactivity with Peripheral Nerve," <i>J. Neurosci. Res.</i> , 44:586-593 (1996).
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C56	Zhang, M and Tracey, K. J., "Tumor Necrosis Factor," in <i>The Cytokine Handbook</i> , (Academic Press Limited), Third Edition, pp. 517-547 (1998).
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 31, 2006 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 3268.1003-004	APPLICATION NO. 10/535,267
		FIRST NAMED INVENTOR Kevin J. Tracey	FILING DATE November 22, 2005
		EXAMINER Not Assigned	CONFIRMATION NO. 6690
			GROUP 1642

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C64	GenBank Accession No. AF165168, "Homo sapiens high mobility group 1-like protein L9 (HMG1L9) retropseudogene complete sequence," (2001) [online] [retrieved on 4/18/2006]. Retrieved from the Internet: <URL: http://www.ncbi.nlm.nih.gov >.	
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C69	Taudte, S., <i>et al.</i> , "Interactions Between HMG Boxes," <i>Protein Eng.</i> , 14(12):1015-1023 (2001).	
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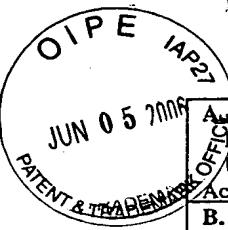
PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 31, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1003-004	APPLICATION NO. 10/535,267
	FIRST NAMED INVENTOR Kevin J. Tracey	FILING DATE November 22, 2005
	EXAMINER Not Assigned	CONFIRMATION NO. 6690
		GROUP 1642

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C75	Jakobovits, A., <i>et al.</i> , "Analysis of Homozygous Mutant Chimeric Mice: Deletion of the Immunoglobulin Heavy-Chain Joining Region Blocks B-Cell Development and Antibody Production," <i>Proc. Natl. Acad. Sci. USA</i> , 90:2551-2555 (1993).
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C79	Pulkki, K., "Cytokines and Cardiomyocyte Death," <i>Ann. Med.</i> , 29:339-343 (1997).
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EXAMINER	DATE CONSIDERED
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COPY



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/36975

A. CLASSIFICATION OF SUBJECT MATTER CPC(7) : C07K 5/00, 16/00; A61K 39/395; C12N 15/00 US CL : 530/350, 387.3, 388.8; 424/134.1, 155.1; 435/69.7 <small>According to International Patent Classification (IPC) or to both national classification and IPC</small>		
B. FIELDS SEARCHED <small>Minimum documentation searched (classification system followed by classification symbols)</small> U.S. : 530/350, 387.3, 388.8; 424/134.1, 155.1; 435/69.7		
<small>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</small>		
<small>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet</small>		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WEN et al. A Human Placental cDNA Clone that Encodes Nonhistone Chromosomal Protein HMG-1. Nucleic Acids Research. 1989, Vol. 17, No. 3, pages 1197-1213, see Figure 6.	1-5.
Y	LODE et al. Targeted Cytokines for Cancer Therapy. Immunologic Research. 2000, Vol. 21, No. 2-3, pages 279-288, see pages 280-281.	7-9.
Y	CZURA et al. Dual Roles for HMGB1: DNA Binding and Cytokine. Journal of Endotoxin Research. 2001, Vol. 7, No. 4, pages 315-321, see entire document, particularly Table 1 and pages 318-319.	10-22, 24-26, 28-35, 37-39, 41-45.
Y	ANDERSSON et al. High Mobility Group I Protein (HMG-1) Stimulates Proinflammatory Cytokine Synthesis in Human Monocytes. Journal of Experimental Medicine. August 2000, Vol. 192, No. 4, pages 565-570, see entire document, particularly page 569.	10-22, 24-26, 28-35, 37-39, 41-45.
Y	US 6,649,172 B2 (JOHNSON) 12 December 2001 (12.12.2001), see column 41.	7-9, 24-26, 37-39.
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report	
09 July 2004 (09.07.2004)	02 AUG 2004	
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306	Authorized officer David J. Blanchard Telephone No. (571) 272-1600	

INTERNATIONAL SEARCH REPORT

International application No.,

PCT/US03/36975

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US03/36975

Continuation of B. FIELDS SEARCHED Item 3:

WEST, Medline, Biosis, cancerlit, biotechno, embase, caplus.

Search terms: HMGB or high mobility group box, HMG-1, immunostimulant, adjuvant, CpG, monophosphoryl lipid A, cancer or tumor, inventor search.